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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,139	04/08/2004	Christopher W. Widenhouse	T2315-907821	6660

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MILES & STOCKBRIDGE PC  
1751 PINNACLE DRIVE  
SUITE 500  
MCLEAN, VA 22102-3833

EXAMINER
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CAMERON, ERMA C

ART UNIT	PAPER NUMBER
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1762

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/820,139	<b>Applicant(s)</b> WIDENHOUSE ET AL.	
	<b>Examiner</b> Erma Cameron	<b>Art Unit</b> 1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2006.  
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.  
 4a) Of the above claim(s) 13 and 15-17 is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 1-12 and 14 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

#### ***Claim Objections***

1. The objection to Claims 1, 3 and 4 is withdrawn because of the amendment filed 3/23/2006.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-12 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) In some claims (2, 9), “agent” is used; in some claims (1, 3, 8), “substance” is used. One term should be used consistently throughout.

b) Claim 1: it is not clear what standard of comparison “enhance” is being used against.

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c) Claim 1: it is not clear if “basic solution” is the same or different from the solution of line 3.

d) Claims 3 and 4 and 10: should be put into proper Markush terminology – selected from the group consisting of.

e) Claim 11: there is no antecedent basis for “the total gamma or electron beam dose”.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The rejection of Claims 1-12 and 14 under 35 U.S.C. 112, first paragraph, (“any pH”), is withdrawn because of the amendment filed 3/23/2006.

### ***Double Patenting***

6. The double patenting rejections are being withdrawn because of the 3/23/2006 amendment.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldberg et al (6387379) taken in view of Darouiche et al (5902283).

'379 teaches treating a silicone or siloxane medical device (7:29-8:61) with monomers such as NVP at 0.1-50% conc. in solution and gamma radiation to polymerize a coating on the medical device. The dose and dose rate overlap with that claimed by applicant (8:63-9:67). The device may get a presoaking in a solution of 5-95% of the grafting monomer (11:1-36). Biofunctional agents such as drugs may be included in the coating (17:44-18:67).

'379 does not disclose that the device surface is hydrolyzed, but because the solution of the applicant and the solution of '379 are the same (same monomers, unlimited pH), it would be inherent that the hydrolysis would take place.

'379 does not teach regulating pH with a metal hydroxide to a pH of >8.

'283 teaches that adding an alkalinizing agent (to a pH of about 12) such as sodium hydroxide to a solution of an antimicrobial composition (such as antibiotics) that is to be applied

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to a silicone medical implant enhances the reactivity of the antimicrobial with the silicone of the medical implant (3:17-4:67; 6:14-18; Example 1).

It would have been obvious to one of ordinary skill in the art to have added the sodium hydroxide of '283 to the '379 process because of the teaching of '283 that the sodium hydroxide enhances the reactivity of a biofunctional agent such as an antibiotic to a silicone surface.

The applicant has argued that '283 does not recognize that pH affects the graft polymerization of monomers to polysiloxane surfaces. However, this effect is inherent to the use of sodium hydroxide and a basic pH.

### ***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Erma Cameron whose telephone number is 571-272-1416. The examiner can normally be reached on 8:30-6:00, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**ERMA CAMERON**  
**PRIMARY EXAMINER**

Erma Cameron  
Primary Examiner  
Art Unit 1762

June 12, 2006